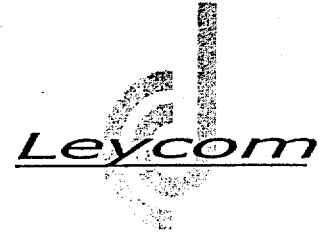


CD Leycom BV

MAY 11 2001

Original 510k Notification for the Cardiac  
Function Laboratory (CFL) & Pressure Volume Catheters**SECTION 2. 510(k) SUMMARY****Submitter**CD Leycom  
Argonstraat 116  
2718 SP Zoetermeer  
The Netherlands**Contact person:**Tim Lenihan,  
VP Catheters and Regulatory Affairs  
Tel: (31) 79 362 1602  
Fax: (31) 79 362 1743  
Mobile phone: (420) 602438997  
E-mail: [info@cardiodynamics.nl](mailto:info@cardiodynamics.nl)**Date summary prepared:** 22.09.00**Device trade name:** 7 Fr Pressure/Volume Catheter (10 mm Electrode spacing),  
product number CA-71103-PN and 7 Fr Pressure/Volume  
Catheter (8 mm Electrode spacing), product number CA-71083-  
PNCardiac Function Laboratory, product number CFL 512  
Pressure Interface, product number SPI-110 & SPI -220**Device common name:** The device is commonly referred to as PV Catheters and  
Pressure Volume Catheters, CFL 512 and Pressure Interface**Device classification name:** Class II at 21CFR 870.1200, Catheter, Intravascular, short term  
Class II at 21 CFR 870.2870, Catheter Tip Pressure Transducer  
Class II at 1 CFR 870.2060 , Transducer Signal Amplifier and  
Signal Conditioner**Legally marketed devices to which the device is substantially equivalent:**

1. K980687 - Sonos 5500 Ultrasound Imaging System, Hewlett-Packard (now Agilent Technologies, Inc.)
2. K830909 - SPC-370 7Fr 120cm Pressure Tip Catheter, Millar Instruments, Inc.

**Description of device:**7Fr Pressure/Volume Catheter with 10mm Electrode Spacing and 7Fr  
Pressure/Volume Catheter with 8 mm Electrode Spacing used with CFL 512 and  
Pressure Interface.The Pressure/Volume Catheter is packaged in a PETG blister and sealed with a  
Tyvek lidstock.

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The CFL-512 uses the conductance catheter technique to measure on-line ventricular volume and, in combination with ventricular pressure measurement, pressure volume loops and relationships can be created or established.

Pressure Interface is a system for continuous measurement of intra arterial and intracardiac pressure in situ.

**Intended use of the device:**

The Pressure, Volume and Pressure-Volume catheters are intended for use with the CD Leycom CFL 512 in conjunctions with a pressure interface module during catheterization laboratory procedures where the quantitative assessment of Left Ventricular function is desired. Refer to the CFL 512 User Manual for a detailed description of the need for pressure and volume measurements in the clinical setting.

Technological characteristics:

The proposed device has the same technological characteristics as the predicate device.

Performance tests:

The following performance tests are included in the submission:

- Animal Testing
- Patient Studies
- Design Verification and Validation testing - catheter
- Safety Testing -CFL

Conclusions:

The results of the animal testing, patient studies, catheter testing and safety testing demonstrate that the device is as safe and effective as the legally marketed predicate devices.



MAY 11 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

CD Leycom BV  
c/o Mr. Tim Lenihan  
Vice President  
Catheters and Regulatory Affairs  
Argonstraat 116  
2718 SP Zoetermeer  
The Netherlands

Re: K003020  
Trade Name: Cardiac Function laboratory (CFL) and Pressure Volume Catheters  
Regulation Number: 870.1200, 870.2870, 870.2060  
Regulatory Class: II (two)  
Product Code: DQO, DXO, DRQ  
Received: February 12, 2001

Dear Mr. Lenihan:

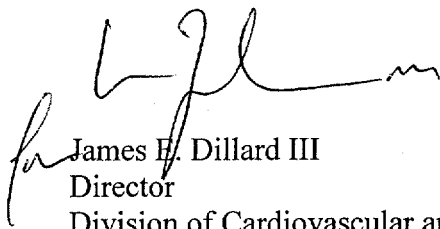
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James H. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

CD Leycom BV

Original 510k Notification for the Cardiac  
Function Laboratory (CFL) & Pressure Volume Catheters

This premarket notification was assembled and reviewed against requirements of the following CDRH guidance documents:

- Guidance on Premarket Notification 510(k) Submission for Short-term and Long-term Intravascular Catheters (03/16/95)
- 6CDRH Premarket Notification (510(k) Refuse to Accept Policy – Final draft 6/30/93)
- Premarket Notification (510(k) Check List for Acceptance Decisions 8/20/93)
- 510(k) "Substantial Equivalence" Decision-Making Process (Detailed) 11/18/91
- Deciding When to Submit a 510(k) for Changes to an Existing Device - Draft 8/1/95
- ISO 10555 -1, -3 Sterile, single-use intravascular catheters (Part 1: General requirements, Part 3: central venous catheters)
- ISO 10993: Biological Evaluation of Medical Devices (Part 1: Evaluation and Testing)
- Premarket Notification 510(k): Regulatory requirements for medical devices
- Supplementary Guidance on the content of Premarket Notification [510(k)] Submissions for medical devices with sharps injury prevention features
- DRAFT VERSION: Electrode Recording Catheter Preliminary Guidance; March 1995
- Guidance for the Content of Premarket Submissions for Software Controlled Medical Devices (5/29/98).

**SECTION 11. INDICATIONS**

510(k) Number (if known) K003020

Device Name: Volume and Pressure Volume Catheters

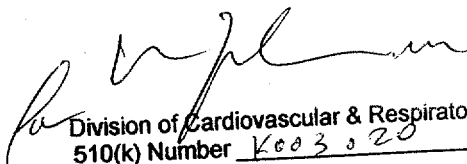
**Indications For Use:**

The Pressure, Volume and Pressure-Volume catheters are intended for use with the CD Leycom CFL 512 in conjunctions with a pressure interface module during catheterization laboratory procedures where the quantitative assessment of Left Ventricular function is desired. Refer to the CFL 512 User Manual for a detailed description of the need for pressure and volume measurements in the clinical setting.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K003020